

REMARKS

Applicants wish to thank the Examiner for the many courtesies extended in the telephonic interview held on Wednesday, April 16, 2008 in which the co-inventors, Dr. Anthony Kinney and Dr. Howard Damude, along with the undersigned participated.

Claim 1 has been amended to recite that the polyunsaturated fatty acid is an omega-3 fatty acid and that the transgenic oilseed plant comprises in its genome at least two transgenic nucleic acid sequences encoding at least two different polypeptides and further wherein at least one polypeptide has desaturase activity and at least one polypeptide has elongase activity. Support for these amendments can be found throughout the specification, Examples and claim 11 as originally filed. Thus, it is believed that no new matter has been added.

Parenthetically, it is noted that certain oilseeds, such as members of the Borage family, blackcurrant seeds and hemp seeds, contain significant amounts of SDA in their oil. Since SDA is already present in these particular seeds, then a single desaturase along with a single elongase is all that would be needed to convert SDA to EPA using the methods described in the instant application.

Claim 21 is currently withdrawn and is being amended to remove dependency from an now cancelled claim.

It is believed that the provisional obviousness-type double patenting rejection in view of claim 1 of copending Application No. 11/624,777 has been obviated in light of currently amended claim 1. Thus, it appears that cancellation of claim 1 of copending Application No. 11/624,777 is no longer needed.

Claims 1, 11-12, 16-18 and 26-28 remain rejected under 35 USC §112, first paragraph, on the ground that the specification is not reasonably enabling for claims broadly drawn to any oilseed plant of any genotype which produced the claimed levels of the claimed fatty acids.

As was noted above claim 1 now recites that the polyunsaturated fatty acid is an omega-3 fatty acid and that the transgenic oilseed plant comprises in its genome at least two transgenic nucleic acid sequences encoding at least two different polypeptides and further wherein at least one polypeptide has desaturase activity and at least one polypeptide has elongase activity. In view of this, Applicants respectfully request withdrawal of the rejection of claims 1, 11-12, 16-18 and 26-28 under 35 USC §112, first paragraph, as lacking enablement.

Claims 1, 11-12, 16-18 and 26-28 remain rejected under 35 USC §112, first paragraph, as failing to comply with the written description requirement. It was stated on page 3 of the Office Action that "...the instant claims are completely silent with regard to the identity of any putative transgene or the enzyme encoded by it."

Claim 1 has been amended to recite that the polyunsaturated fatty acid is an omega-3 fatty acid and that the transgenic oilseed plant comprises in its genome at least two transgenic nucleic acid sequences encoding at least two different polypeptides and further wherein at least one polypeptide has desaturase activity and at least one polypeptide has elongase activity.

In view of this, Applicants respectfully request withdrawal of the rejection of claims 1, 11-12, 16-18 and 26-28 under 35 USC §112, first paragraph, as failing to comply with the written description requirement.

The Examiner's presumption that the subject matter of the various claims was commonly owned at the time that the invention(s) covered therein were made is indeed correct.

Claims 1, 16 and 26 were rejected under 35 USC §103(a) as being unpatentable over Knutzon et al. (US 6,075,183 issued June 2000), in view of Abbott Laboratories (WO 02/08401 effectively filed July 2000), further in view of Biooriginal Food & Science Corporation (WO 02/26946) effectively filed 2000). It was kindly noted on page 5 of the Office Action that these reference had been submitted by Applicant. The basis of this ground of rejection is that it "would have been obvious to one of ordinary skill in the art to utilize the method of Brassica transformation with the delta-5 and delta-6 desaturase genes under the control of the seed-specific napin promoter for the production of novel PUFAs in the seed oil of transgenic plants as taught by Knutzon et al, and to modify that method by incorporating the elongase genes taught by ABBOTT LABORATORIES under the control of a seed-specific promoter, and to further modify that method by incorporating the delta 4 desaturase gene taught by BIORINGINAL FOOD & SCIENCE under the control of the seed-specific napin promoter, to obtain transgenic Brassica seeds producing oil with at least 1% of omega-6 DPA, as suggested by each reference."

Claim 1 now recites, *inter alia*, that the polyunsaturated fatty acid is an omega-3 fatty acid and that the transgenic oilseed plant comprises in its genome at least two transgenic nucleic acid sequences encoding at least two different

polypeptides and further wherein at least one polypeptide has desaturase activity and at least one polypeptide has elongase activity.

It is respectfully submitted in view of this that it would not have been obvious to one of ordinary skill in the art to combine the references as discussed on page 7 of the Office Action to obtain a transgenic oilseed plant that produces mature seeds in which the total seed fatty acid profile comprises at least 1.0% of at least one omega-3 polyunsaturated fatty acid having at least twenty carbon atoms and five or more carbon-carbon double bonds wherein said transgenic oilseed plant comprises in its genome at least two transgenic nucleic acid sequences encoding at least two different polypeptides and further wherein at least one polypeptide has desaturase activity and at least one polypeptide has elongase activity.

Accordingly, withdrawal of the rejection of the claims 1, 16 and 26 as being unpatentable under 35 USC §103(a), is respectfully requested in view of the amendment of claim 1 and foregoing discussion.

Claims 1, 11-12, 16-18, 26-28 and 141 were rejected under 35 USC §103(a) as being unpatentable over Knutson et al. (US 6,075,183) in view of Abbott Laboratories (WO 02/08401 effectively filed July 2000), further in view of each Mukherji et al. (US 7,211,656 effectively filed January 2002) or Browse et al. (US 6,884,921 effectively filed February 1997).

The basis of this ground of rejection is that it “would have been obvious to one of ordinary skill in the art to utilize the method of Brassica transformation with the delta-5 and delta-6 desaturase genes under the control of the seed-specific napin promoter for the production of novel PUFAs in the seed oil of transgenic plants as taught by Knutson et al, and to modify that method by incorporating the elongase genes taught by ABBOTT LABORATORIES under the control of a seed-specific promoter, and to further modify that method by incorporating the omega-3/delta 17 desaturase genes taught by Mukherji et al or Browse et al under the control of a seed-specific promoter such as the napin promoter for the production of EPA in the oil of the transgenic Brassica seeds, as suggested by each reference.”

Knutson describes the production of GLA and STA. The Abbott, Bioriginal and Browse patents disclose LCPUFA elongases and desaturases. GLA and STA are found in the oils of some plants.

It is respectfully submitted that it would not have been obvious to combine the aforementioned references for the reasons set forth hereinbelow.

Synthesis of of GLA and STA is a single linear conversion from LA or ALA.

In contrast, EPA and DHA are membrane lipids not normally found in any plant oil. Synthesis of EPA from endogenous plant lipid is not linear. Prior to the instant invention, it was not known if a plant could accumulate these fatty acids in their oil.

Fatty acids are desaturated while part of membrane lipids, they are elongated while attached to acyl-CoA. Thus, fatty acids need to pass in and out of the phospholipids in the plant cell membrane as part of the pathway to synthesizing EPA. This step was thought to be a major block in converting ALA to EPA in plants (as described by Robert, copy previously submitted). Consequently, this led researchers to look for acyltransferases involved in the exchange of acyl groups between membrane lipids.

In Wu et al, cited by Robert, the investigators use the same method disclosed in the instant application to make 15% EPA in *Brassica* seeds. When an additional acyltransferase is added to the constructs, there appeared to be no effect on the total EPA content. Robert also describes an attempt by his own group to look for acyl-CoA desaturases from fish and express them in plants in an effort to avoid having fatty acids pass in and out of membrane phospholipids. It was concluded, however, that this is not necessary and, in the light the information disclosed in the instant application, should essentially use the methods described in the instant application to design LCPUFA pathways.

Likewise, the synthesis of DHA from EPA in higher organisms is a complex series of events involving two acyl-CoA elongation reactions, movement to membrane phospholipids, a membrane desaturation., movement of the resultant fatty acid into the peroxisome and then a beta-oxidation reaction to produce DHA.

Accordingly, it would not have been obvious to one of ordinary skill in the art that adding a delta-4 desaturase to transgenic seeds designed to produce EPA using the methods disclosed in the above-identified application, would lead to the formation of DHA given the complexity of the pathway.

Applicants respectfully request consideration of the possible rejoinder of claims 21 and 140 in the event that claim 1 is found to be allowable. Claims 21 and 140 depend from claims 1 or 12 and incorporates all the limitations thereof.

Please charge any fees or credit any overpayment of fees which are required in connection with the filing of this Response to Deposit Account No. 04-1928 (E. I. du Pont de Nemours and Company).

It is respectfully submitted that the claims are now in form for allowance which allowance is respectfully requested.

Respectfully submitted,

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